

REMARKS

Claims 1-22 are currently pending in the present application. Claims 5, 9 and 13-19 are currently withdrawn from consideration. Claim 1 has been amended and support can be found, for example, in the specification at paragraph [0022]. Claim 10 has been amended and support can be found, for example, in paragraph [0015] of the specification. New claim 20 is added and support can be found, for example, in Figure 1; new claim 21 is added and support can be found, for example, in Figure 2; and new claim 22 is added and support can be found, for example, in Figure 4.

Election/Restriction

In the present Office Action, the Examiner has indicated that claim 9 is withdrawn from consideration. Applicants submit that this is an improper designation. The Examiner has miscategorized both claims 5 and 9 as being directed to “different compositions.” Claim 5 states that the *therapeutic agents* are different compositions and claim 9 states that the *coatings* are different compositions.

In the Election of Species Requirement of September 29, 2005, the Examiner presented Species B(c) directed to applying a first and a second *therapeutic agent* that are each different and Species B(d) directed to applying a first and second *therapeutic agent* that are each the same. Applicants elected Species B(d). In the Response, Applicants pointed out that claim 9 is readable on Species B(d) because the claim recites that the first and second coatings are different compositions and therefore encompasses methods where the same *therapeutic agent* is in each of the first and second coatings. As such, Applicants argued that claim 9 is readable on Species B(d). The Examiner appeared to have agreed, since the Office Action of November 15, 2005 did not state that claim 9 was withdrawn and the Examiner included claim 9 in the art rejection. Being that claim 9 has already been searched, the Applicants submit that claim 9 is not withdrawn and is under consideration. Furthermore, in the Advisory Action of December 27, 2006, the Examiner stated that she “agrees that claim 9 is not withdrawn.” Thus, Applicants believe that claim 9 was mistakenly indicated as withdrawn and is still under consideration.

Rejection under 35 USC 112, 1st paragraph

Claims 1-4, 6-8 and 10-12 are rejected under 35 USC 112, 1st paragraph, as allegedly failing to comply with the enablement requirement. With respect to claim 4, the Examiner states that it is not clear what a reservoir is and it has not been defined. A reservoir is a “part of an apparatus where a liquid is held” (Merriam-Webster Dictionary), which is well-known to one of ordinary skill in the art. Furthermore, paragraph [0021] states that reservoirs “could be created in the single coating, such as by heat, UV, chemical, or laser source.” The reservoirs created in the coating provide a location for the first and second therapeutic agents to be placed. With respect to the other claims listed in this rejection, the Examiner does not point to any specific limitations or subject matter that she believes lack enablement. Thus Applicants believe this rejection should be withdrawn.

Rejection under 35 USC 112, 2nd paragraph

Claims 4 and 10 are rejected under 35 USC 112, 2nd paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As discussed above, with respect to claim 4, the term reservoir is well-known in the art and is not indefinite.

Claim 10 has been amended to clarify that the target site is a blood vessel and thus the flow rate relates to the blood flow at the target site where the medical device is placed. Applicants believe these rejections should be withdrawn.

Rejection under 35 USC 102

Claims 1, 3, 4 and 6 are rejected under 35 U.S.C. §102(b) for being allegedly anticipated by U.S. Patent 5,679,400 to Tuch (“Tuch”). Applicants respectfully traverse this rejection. Tuch describes a method of coating stents by repeatedly applying multiple thin coats of a drug solution to the *same portion* of a stent and weighing the stent, until the target dosage is reached. Claim 1 recites applying a first desired amount of therapeutic agent to a first portion, determining how much of the therapeutic agent was

actually applied, and then applying a second amount of therapeutic agent to a second portion, wherein the second amount is the difference between the first desired amount and the first actual amount, and the *first and second portions are different*. To anticipate a claim, the reference must disclose each and every element of the claimed invention. *Verdergaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Although Tuch describes applying multiple thin coats of a polymer/drug solution to a stent “with drying and weighing of the stent between coats,” (col 2, line 61), Tuch does not provide any disclosure of applying successive coats to *different portions* of the stent. As such, Tuch does not disclose each and every element of claim 1.

With regard to claim 4, a “layer” is clearly not the same thing as a “reservoir” to one of ordinary skill in the art. A layer is defined as “one thickness, course, or fold laid or lying over or under another” (Merriam-Webster Dictionary). Thus, although a layer may include a therapeutic agent, it is not considered to be a reservoir.

For at least these reasons, Applicants submit that claims 1, 3, 4 and 6 are not anticipated by Tuch and Applicants request withdrawal of this rejection.

Rejection under 35 USC 103

Claims 2, 7, 8 and 10-12 are rejected under 35 U.S.C. §103(a) for being allegedly rendered obvious by Tuch. Applicants traverse this rejection. As discussed above, Tuch does not disclose all the limitations of claim 1, and thus does not disclose the limitations of those claims dependent therefrom. Furthermore, there is no teaching or suggestion in Tuch to modify the method to sequentially coat two *different* portions of the stent.

Furthermore, claim 2 recites that the first portion has a greater surface area than the second portion. The Examiner completely fails to address this limitation, and rather assumes that the first and second portions are the same portion, which would not be possible with two different surface areas. There is no disclosure, teaching or suggestion of this limitation in Tuch.

Additionally, claim 7 recites the first portion is exposable to a first area of a target site and the second portion is exposable to a second area of a target site. This limitation is also improperly interpreted by the Examiner, since the first portion and the

second portion cannot be exposable to two different areas of the target site if they are the same portion. The amendment to claim 1 further clarifies that the first and second portions are different portions, which is clearly not disclosed, suggested or taught by Tuch.

For at least these reasons, Applicants submit that claims 2, 7, 8 and 10-12 are not rendered obvious by Tuch and Applicants request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
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Date: October 15, 2007

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